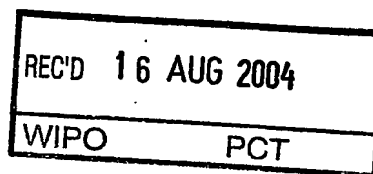


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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 30 July 2003 with an application for Letters Patent number 527313 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 5 August 2004.

A handwritten signature in cursive script that reads "Neville Harris".

Neville Harris
Commissioner of Patents, Trade Marks and Designs



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Intellectual Property
Office of NZ ty

30 JUL 2003

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PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Breathing Assistance Apparatus"

We, FISHER & PAYKEL HEALTHCARE LIMITED, a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

FIELD OF INVENTION

This invention relates to patient interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA). In particular the present invention relates to mask forehead rest pads.

5 BACKGROUND OF THE INVENTION

In the art of respiration devices, there are well known variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face such that gas may be provided at positive pressure within the mask for consumption by the user. The uses for such masks range from high altitude breathing
10 (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

One requisite of such respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with
15 considerable discomfort for the user. This problem is most crucial in those applications, especially medical applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

20 US Patent No. 5,243,971 and US Patent No. 6,112,746 are examples of prior art attempts to improve the mask system. US Patent No. 5,570,689 and PCT publication No. WO 00/78384, and US Patent No. 6,119,693 are examples of attempts to improve the forehead rest.

SUMMARY OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface which goes
25 some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

Accordingly in a first aspect the present invention may broadly be said to consist in a device for delivering a supply of gases to a user comprising:

a patient interface, in use in fluid communication with said supply of gases,
30 a forehead rest engaging said interface including a deformable resilient member configured to in use rest against the face of a patient, said deformable resilient member when compressed in use creating a uniformly and gradually increasing force, while evenly distributing the pressure on

the forehead of said patient that contacts said resilient member.

Preferably said deformable resilient member has a top surface and a base connected by two side walls, said side walls being thin and in use are compressible.

Preferably said top surface is substantially thicker than said side walls.

5 Preferably said top surface includes additional support at its centre to limit its collapse.

Preferably said side walls are capable of folding under compression.

Preferably said deformable resilient member is moulded from silicone.

Alternatively said deformable resilient member is extruded from silicone.

10 In a second aspect the present invention may broadly be said to consist in a device for delivering a supply of gases to a user comprising:

(a patient interface, in use in fluid communication with said supply of gases,

a forehead rest engaging said interface including a deformable resilient member configured to in use rest against the face of a patient, said deformable resilient member being of a hollow conical shape where in use and under compression the top part of said hollow cone deforms or the
15 side walls of said cone deform.

Preferably said deformable resilient member is moulded from silicone.

Alternatively said deformable resilient member is extruded from silicone.

In a third aspect the present invention may broadly be said to consist in a device for delivering a supply of gases to a user comprising:

20 a patient interface, in use in fluid communication with said supply of gases,

(a forehead rest engaging said interface including an adjustable deformable resilient member configured to in use rest against the face of a patient.

Preferably said adjustable deformable resilient member is at least one adjustable strap attached and adjustable on said forehead rest.

25 Alternatively said adjustable deformable resilient member is a member rotatably mounted on said forehead rest.

Alternatively said adjustable deformable resilient member is an inflatable member that is inflated with liquid or gas.

30 This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention

relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

5 **Figure 1** is a block diagram of a humidified continuous positive airway pressure (system) as might be used in conjunction with the present invention,

Figure 2 is an illustration of the nasal mask in use according to the preferred embodiment of the present invention,

Figure 3 shows a perspective view of the mask with cushion,

10 **Figure 4** is a cutaway view of the mask showing the cushion,

Figure 5 is a cutaway view of the periphery of the outer membrane,

Figure 6 is a cutaway view of the periphery of the mask body portion,

Figure 7 shows a prior art forehead rest in isolation,

Figure 8 shows a section view of the prior art forehead rest of Figure 7,

15 **Figure 9** shows a perspective view of the forehead rest cushion of Figure 7,

Figure 10 is a section of a further prior art forehead rest cushion,

Figure 11 is a section of perspective view of the forehead rest cushion of Figure 10,

Figure 12 is a back view showing the slots in the forehead rest for each cushion to lock into,

20 **Figure 13** is a perspective view of a first embodiment of a forehead rest cushion of the present invention,

Figure 14 is a perspective view of a second embodiment of a forehead rest cushion of the present invention,

Figure 15 is an alternative perspective view of the forehead rest cushion of Figure 14,

25 **Figure 16** is a section of the forehead rest cushion of Figure 14,

Figure 17 is a side view of a third embodiment of a forehead rest cushion of the present invention,

Figure 18 is an alternative perspective view of the forehead rest cushion of Figure 17,

Figure 19 is a section view of the forehead rest cushion of Figure 17,

30 **Figure 20** is a perspective view of a fourth embodiment of a forehead rest cushion of the present invention,

Figure 21 is a section of the forehead rest cushion of Figure 20,

Figure 22 is a perspective view of a fifth embodiment of a forehead rest cushion of the present invention,

Figure 23 is a sixth embodiment of a forehead rest cushion of the present invention,

5 Figure 24 is a seventh embodiment of a forehead rest cushion of the present invention,

Figure 25 is a perspective view of an eighth embodiment of a forehead rest cushion of the present invention,

Figure 26 is a perspective view of a ninth embodiment of a forehead rest cushion of the present invention,

10 Figure 27 is a perspective view of a tenth embodiment of a forehead rest cushion of the present invention, where the forehead rest cushion is adjustable to a user's requirements,

Figure 28 is a perspective view of an eleventh embodiment of a forehead rest cushion of the present invention, this embodiment also being incapable of being adjusted by the user,

15 Figure 29 is a perspective view of a twelfth embodiment of the forehead rest cushion of the present invention, where the forehead rest cushion is adjustable,

Figure 30 is a perspective view of a thirteenth embodiment of a forehead rest cushion of the present invention, this embodiment also being adjustable,

Figure 31 is a perspective view of a fourteenth embodiment of a forehead rest cushion of the present invention,

20 Figure 32 is a perspective view of a fifteenth embodiment of a forehead rest cushion of the present invention, and

Figure 33 is a perspective view of a sixteenth embodiment of a forehead rest cushion of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 The present invention provides improvements in the delivery of CAP therapy. In particular a patient interface is described which is more comfortable for the user to wear and reduces leakage as compared with the prior art. It will be appreciated that the patient interface as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator but will now be described below with reference to use in a humidified CPAP system. It will also be appreciated that the present invention can be applied to
30 any form of patient interface including, but not limited to, nasal masks, oral masks and

mouthpieces.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 which contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources, for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a gases supply means or blower 15 which enters the chamber through inlet 16. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 21 which draws air or other gases through blower inlet 17. The speed of variable speed fan 21 is controlled by electronic controller 18 (or alternatively the function of controller 18 could be carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 19.

Nasal Mask

According to a first embodiment of the present invention the patient interface is shown in Figure 2 as a mask. It will be appreciated the patient interface could equally be a nasal mask, full face, oral mask or mouth piece, endotracheal tube or cannula by way of example. The mask includes a hollow body 102 with an inlet 103 connected to the inspiratory conduit 3. The mask 2 is positioned around the nose of the user 1 with the headgear 108 secured around the back of the head of the patient 1. The restraining force from the headgear 108 on the hollow body 102 and the forehead rest 106 ensures enough compressive force on the mask cushion 104, to provide an effective seal against the patient's face.

The hollow body 102 is constructed of a relatively inflexible material for example, polycarbonate plastic. Such a material would provide the requisite rigidity as well as being transparent and a relatively good insulator. The expiratory gases can be expelled through a valve (not shown) in the mask, a further expiratory conduit (not shown), or any other such method as is known in the art.

Mask Cushion

Referring now to Figures 3 and 4 in particular, the mask cushion 1104 is provided around the periphery of the nasal mask 1102 to provide an effective seal onto the face of the user to prevent leakage. The mask cushion 1104 is shaped to approximately follow the contours of a patient's face. The mask cushion 1104 will deform when pressure is applied by the headgear 1108 to adapt to the individual contours of any particular user. In particular, there is an indented section 1150 intended to fit over the bridge of the user's nose as well as a less indented section 1152 to seal around the section beneath the nose and above the upper lip.

In Figure 4 we see that the mask cushion 1104 is composed of an inner foam cushion 1110 covered by an outer sealing sheath 1112. The inner cushion 1110 is constructed of a resilient material for example polyurethane foam, to distribute the pressure evenly along the seal around the user's face. The inner cushion 1110 is located around the outer periphery 1114 of the open face 1116 of the hollow body 1102. Similarly the outer sheath 1112 may be commonly attached at its base 1113 to the periphery 1114 and loosely covers over the top of the inner cushion 1110.

In the preferred embodiment shown in Figures 3-6 the bottom of the inner cushion 1110 fits into a generally triangular cavity 1154 in the hollow body 1102. The cavity 1154 is formed from a flange 1156 running mid-way around the interior of the hollow body.

The outer sheath 1112 fits in place over the cushion 1110, holding it in place. The sheath

1112 is secured by a snap-fit to the periphery 1114 of the hollow body. In Figures 5-6 the periphery 1114 is shown including an outer bead 1158. The sheath 1112 includes a matching bead 1159, whereby once stretched around the periphery, the two beads engage to hold the sheath in place.

5 Forehead Rest

A prior art nasal mask 102 including a forehead rest 106 is shown in Figures 2 and 7. The forehead rest 106 may move freely in proximity to the mask body 102 and user, but with no lateral movement or may be permanently fixed or adjustably fixed.

Referring to Figure 7, at the top end 142 (around the user's forehead) of the bridge member 136 harnessing slots (not shown) are provided which allow straps from the headgear to be inserted to secure the mask to the headgear. For the user's comfort one or more resilient cushions 140 are provided on the T-piece of the forehead rest 142 the top end of the bridge member 136, to rest on the forehead of the user. The cushion 140 is constructed by injection moulding or extruding, from silicone or any foam materials as is known in the art for providing cushioning. In Figure 7 a second cushion 143 is shown at the other end of the section 142.

Forehead Rest Cushion

Referring now to Figures 8 and 9 the prior art forehead rest cushion 140 is illustrated. The cushion 140, in cross section, includes an outer curved member 210 and an inner curved member 212 both of which are attached at each end to a straight base member 214. The inner curved member 212 is a substantially similar curved shape to the outer curved member 210. The inner member 212 and outer member 210 may be coterminous, the inner member may attach to the outer member 210 or both may attach to the base 214 separately.

When the cushion 140 comes into contact with the user's face the outer curved member 210 deforms as more pressure is applied to the cushion towards the face. This comprises of the first mode of deformation. Once the outer curved member 210 deforms enough to contact the inner curved member a second mode of deformation occurs.

As will be appreciated if the outer curved member is flatter than the second curved member 212 the first mode requires less force. The relative curvature and thickness of each can be varied to give a characteristic first mode and second mode. Once in the second mode of deformation extra force is required to deform both the first curved member 210 and the second curved member 212. This configuration described above results in more even deformation force across the load bearing surface of the cushion 216 and also results in a more progressive force of cushioning

when the cushion 120 is deformed.

A further prior art embodiment of a forehead rest cushion is shown in Figures 10 and 11. This forehead rest cushion 140 has an outer curved member 220 attached at either end to a straight base member 222. A inner inverted curved member 224 is inverted with respect the outer curved member 220 and is attached at either end two points on the 226, 228 on the outer curved member 220. The inner inverted curved member is lower in overall height than the outer curved member 220 such that a first mode of deformation occurs when the outer curved member 220 is deformed. A second mode of deformation occurs when the inner inverted curved member 224 contacts the base member 222. The outer curved member 220 and the inner inverted curved member 224 deform simultaneously. The forces across the load bearing surface 230 are further distributed by virtue of a generally quadrilateral member 232 including as one side the base member 222 which attaches over the inner inverted curved member 220 approximately at its ends and at its load bearing point 234. The quadrilateral member 232 provides additional stiffness and reduces lateral deformation.

These prior art forehead rests have a base member that includes a flange 240 which engages with a slot 2138 in the forehead rest 106 to lock the forehead rest cushion in place. The flange 240 first slides through aperture 2139 as seen in Figure 12.

In the preferred forms of the forehead rest cushion of the present invention will now be described with reference to Figures 13 to 26, 31 and 32. With each of the embodiments as described in relation to these figures the forehead rest cushion or pad allows for a controlled compression of the cushion. Each cushion is capable of being compressed under a force and will return to its original position (as shown in the Figures) when the force ceases.

A first embodiment of the forehead rest cushion is shown in Figure 13. This forehead rest cushion 300 has a flange 301 that is able to be attached to a forehead rest, such as that rest 106 shown in Figure 7 or 12. The flange 301 slides through the aperture 2139 in the T-piece 2140 of the forehead rest 106. The cushion 300 is substantially rectangular in shape with an upper wall 302 and lower wall 303, with the flange being attached to the lower wall 303. The side walls are corrugated or concertinaed such that these walls 304, 305 collapse when a force is placed on the upper wall 302. As described above, as the cushions are made from a plastics material, such as silicone or foam, the folds forming the side walls will return to the original form when any compression force ceases.

Figure 14 shows a second embodiment of a forehead rest cushion of the present invention.

This forehead rest cushion 306 is a cushion that is in the general shape of a parabolic cone. The cushion has an open top 307 that can be seen in Figure 15, this open top 307 allows the edge 308 of the cushion 306 to roll inwards when the top of the cone shaped cushion is compressed, or a force placed air on. This cushion may be attached to a forehead rest, such as the T-piece forehead rest as shown in Figures 7 and 12 by any appropriate means, for example, gluing or the like and may include a flange such as that described above with reference to Figure 13.

In alternative embodiments any of the forehead rest cushion of the present invention as shown in the Figures may have an alternative attachment mechanism such as an arrow head type barb or protrusion, which fits into apertures on the forehead rest. Alternatively, any of the cushions may be provided with an aperture in place of the flange that is able to be slid about an arm of the forehead rest.

A third embodiment of the forehead rest cushion of the present invention is shown in Figures 17, 18 and 19. This cushion 309 has a conical body 310 with a flattened circular top 311.

This cushion is either injection moulded, extruded, or stamped from a sheet of material and is preferably made of a thermoplastic elastomer, silicone or foam. Again, when a force is applied to the top 311 the inner areas of the top roll inwards down towards the top of the cone body 310. For example, as shown in Figure 19 in a section view when a force A is placed on the top 311 the inner area of the top 311 moves downwards and the outer areas, shown as 311', move upwards or simply adjust to the shape of the area of user's forehead it abuts.

Reference is now made to Figures 20 and 21 where the force embodiment of the forehead rest cushion of the present invention is shown this forehead rest cushion 312 is of a hemispherical shape and also allows for a two stage cushioning when a force is placed upon it. The cushion 312 has a hemispherical body 313 suspended above a platform 314 and also has a flange 315 allowing the cushion 312 to be slotted into an aperture in a forehead rest, such as that described above. The hemispherical body 313 is suspended above platform 314 on small supports 316, 317. This cushion 312 is preferably moulded from a thermoplastics material, silicone or foam.

A fifth embodiment of the forehead rest cushion is shown in Figure 22. The cushion 318 is shaped in the form of an "M" or generally rectangular with a recess 319 formed in the top wall 320 of the cushion 318. Therefore, two inner vertical walls 321, 322 are formed parallel to the outer vertical walls 323, 324. When a force is applied to the upper wall 320 the recessed part 319 and vertical walls 322, 321 are pushed downwards towards the lower wall 325. When the apex 326 of the recessed part 319 hits the lower wall 325 the cushion may still be compressed, but at a

different rate of force such that the compression of this cushion 318 is a two stage compression. The recess 319 in the middle of the cushion 318 therefore provides more uniform pressure across the top wall 320 of the cushion. As with other forms as described above this forehead cushion 318 is supplied with a flange 327 attached to the lower wall 325 allowing the cushion 318 to be
5 attached to the forehead rest.

Reference is now made to Figure 23 where a sixth embodiment of the forehead rest cushion of the present invention is shown. This cushion 328 is of a similar form to that described in relation to Figure 13, but its top or upper wall 329 is curved and the side walls 330, 331 merely form one corrugation or fold. When a force is placed upon the upper wall 329 the side walls 330,
10 331 fold in upon themselves. Again, this cushion has a flange 332 attached to its lower wall 333 to allow the cushion 328 to be attached to the forehead rest.

A seventh embodiment of the forehead rest cushion as shown in Figure 24, this cushion is very similar in form to that of the prior art cushion as shown in Figure 8 but its upper wall 335 is split in two and its inner wall 336 is horizontal in nature and not curved. Again, this cushion 334
15 has a flange 337 that allows it to be attached to a forehead rest. This cushion provides a two stage compression where the inner wall provides stability to the cushion 334.

The eighth embodiment of the forehead rest cushion of the present invention is shown in Figure 25. This cushion 318 has a base member 319 having a flange similar to as described above in relation to the prior art cushions. The flange 340 allows the cushion 338 to be attached to a
20 forehead rest. Two vertical walls 341, 342 extend upwards nearer the centre of the base member 339, and a curved upper member in the shape of a partial oval is attached above the vertical walls 341, 342. When a force is placed on the curved upper member 343 the vertical walls 341, 342 initially support the force placed on the upper member 343. The outer edges 344, 345 of the upper member 343 are able to freely roll inwards to give further controlled support to the cushion
25 338.

A ninth embodiment of the forehead rest cushion of the present invention is shown in Figure 26. This cushion 346 has a base member 347 and a flange attached to it to enable the cushion to be attached to a forehead rest. Extending outwards and upwards from the edges of the base member 347 are arms 349, 350. These arms 349, 350 are curved inwardly towards one
30 another and may overlap. When a force is placed on the upper 350 arm, the arm 350 moves down towards the lower arm 349. If enough force or a continued force is provided to the upper arm 350, the upper arm 350 will continue to compress against and push the lower arm 349 towards the

centre of the cushion 346 and the base member 347. These independent inwardly rolled arms 349, 350 allow for a two stage compression that is controlled when a force being placed on the upper arm 350.

5 A fourteenth embodiment forehead rest cushion of the present invention is shown in Figure 31. This cushion 351 has a similar shape to the prior art cushion of Figure 9 and includes a base member 354 and a flange 353 which engages with a slot 2138 in the forehead rest to lock the forehead rest cushion in place. The flange 353 slides through and fixes in the aperture 2139 as seen in Figure 12. The cushion 351 is substantially rectangular in shape but with an upper wall 352 that is slightly curved at its edges where it meets the side walls 355, 356 of the cushion. The upper wall is thicker in width than the side walls 355, 356 to provide additional strength and control to the cushion. Furthermore, the relative thickness of the upper wall 352 compared to the side walls 355, 356 prevents the cushion 351 from caving in. This helps provide a uniform pressure on the user's forehead.

15 A further embodiment of a forehead rest cushion is shown in Figure 32. This cushion 357 is exactly the same shape as that cushion of Figure 31, but this cushion has an additional curved short wall 358 extending below and following the contour of the upper wall 359. This short wall 358 provides for additional support to the upper wall 359 when a force is placed upon it.

20 Figures 27 to 30 and 33 illustrate forehead rest cushions that can be adjusted to a user's preference. Firstly referring to Figure 27 a rotating substantially circular or cam shaped cushion 360 rotatably mountable between two legs 361, 362, which are each attached and extend outwards from the forehead rest or mask base, for example, one on either side of the T-piece as shown in Figure 12. As the cushion 360 rotates in the direction of Arrow B the offset is increased or decreased.

25 Figure 28 shows a further embodiment of the cushion of Figure 27. This cushion 363 additionally has a plurality of fixed attachments 364, similar to the flange on the cushions described above. Each of these can be attached to the forehead support in turn to provide an adjustable cushion.

30 A twelfth embodiment of a forehead rest cushion of the present invention is shown in Figure 29. This cushion 365 is effectively a strap or flexible elongate member (preferably made of a flexible plastics material) attached to one arm 366 of a T or to an I piece of a forehead rest. In the case of a T-shaped forehead rest, such as that shown in Figure 12, two cushions of this type would be provided one for each of the two arms of the T-shaped forehead rest. The strap 365 is

provided with a pair of protrusions 367, 368 at each of its ends 369, 370 such that a recess is formed between each set of protrusions. Each end 369, 370 is fixed to the arm 366 by appropriate means, such as a sleeve 371 or aperture 372 on the arm 366. In particular, the upper end 369 of the strap 365 is fixed to the arm 366 in the aperture 372 and the lower end 370 is slideably adjustable by way of a slideable sleeve 371 capable of sliding and being fixed into any one of a number of recesses 373 formed on the edge 374 of the arm 366.

A further embodiment of an adjustable forehead rest cushion is shown in Figure 30. This adjustable cushion 375 is a strap or flexible elongate member where a first end 376 of its two ends 376, 377 is fixed to an arm 379 (similar to that arm 366 described above). The second end 377 of the two ends is threaded about and around such that a substantial part of the strap forms a circular shape that provides a cushioning effect should a force be placed upon it. The second end 377 after being threaded through an aperture 381 in the arm 379, and possibly an further holding sleeve 380 formed on the arm 379, is fixed to the other side of the arm 379, for example by pressing a protrusion 382 through a hole 383 formed in the strap 375. The size of the circular cushion formed can be adjusted as a plurality of spaced apart holes are provided in the strap and the strap can be pulled through the arm and the protrusion 382 fixed in each hole dependent on the requirements of the user.

Yet still a further embodiment of an adjustable forehead rest cushion is shown in Figure 33, where a double loop strap 384 is formed into two arced cushions 385, 386. Each of the apexes of the arced cushions 385, 386 would in use rest against a user's forehead to provide additional comfort while wearing a mask or interface similar to that described above. The strap 384 has abutments 387, 388 formed at each end that fit under lips 389, 390 formed in an arm 391 (such as, a one T-piece arm of the forehead rest as described above in relation to Figure 12, or an I shaped forehead rest as is known in the prior art and particularly described in New Zealand patent application number 524439 of Fisher & Paykel Healthcare Limited). The middle section 392 of the strap 384 has a plurality of notches 393 cut in each of its edges. The strap 384 is threaded through two apertures formed in the middle of the arm 391, such that a substantial portion of the middle section 392 extends out from the arm 391 in an opposing direction to the arced cushions 385, 386. The middle section 393 can be pulled further through the arm or to pushed back through the apertures in the arm using the notches 393 as incremental positions for the middle section to be held in, to decrease or increase the size of the arced cushions 385, 386.

In other forms of the forehead rest cushion of the present invention the cushion may be an

inflatable member that can be manually inflated using a syringe or a hand or finger operated compression pump, or automatically inflated using a compressible reservoir or the like.

DATED THIS 30th DAY OF July 2003
AJ PARK
PER N. Chelley
AGENTS FOR THE APPLICANT

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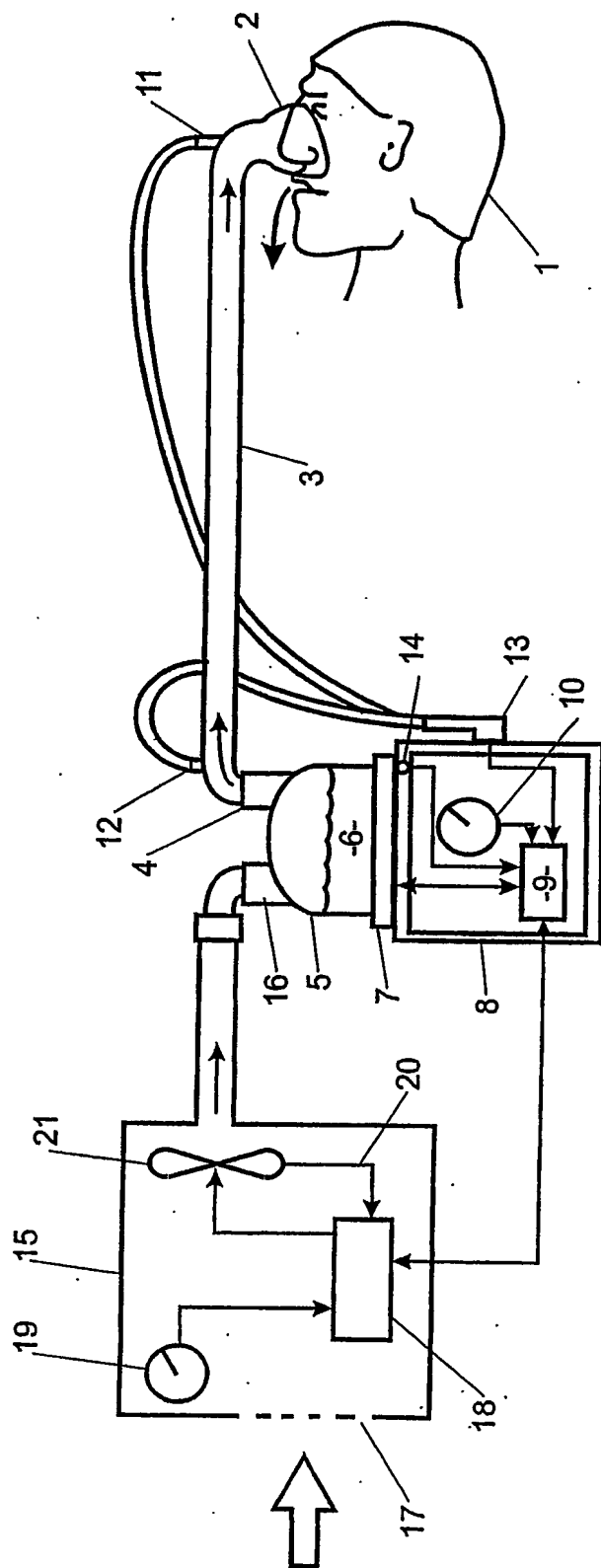


Figure 1

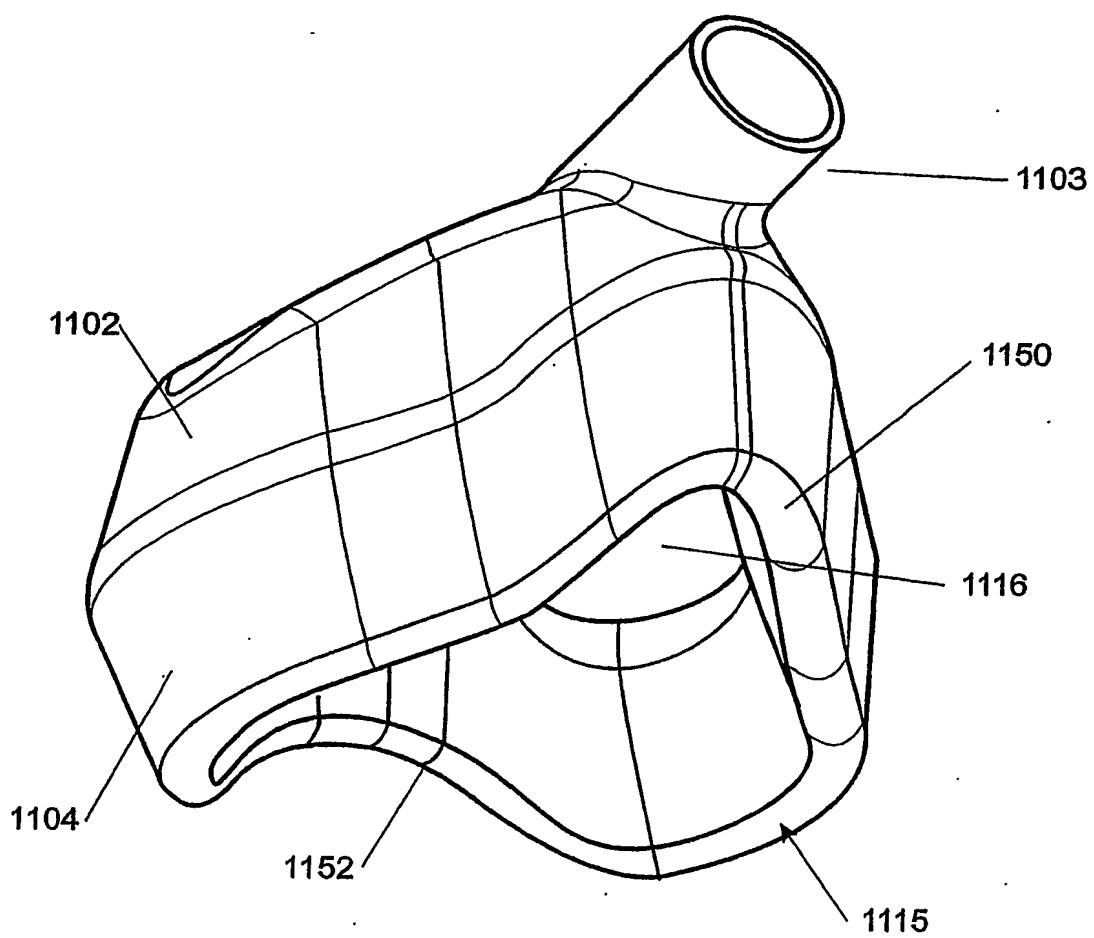


Figure 3

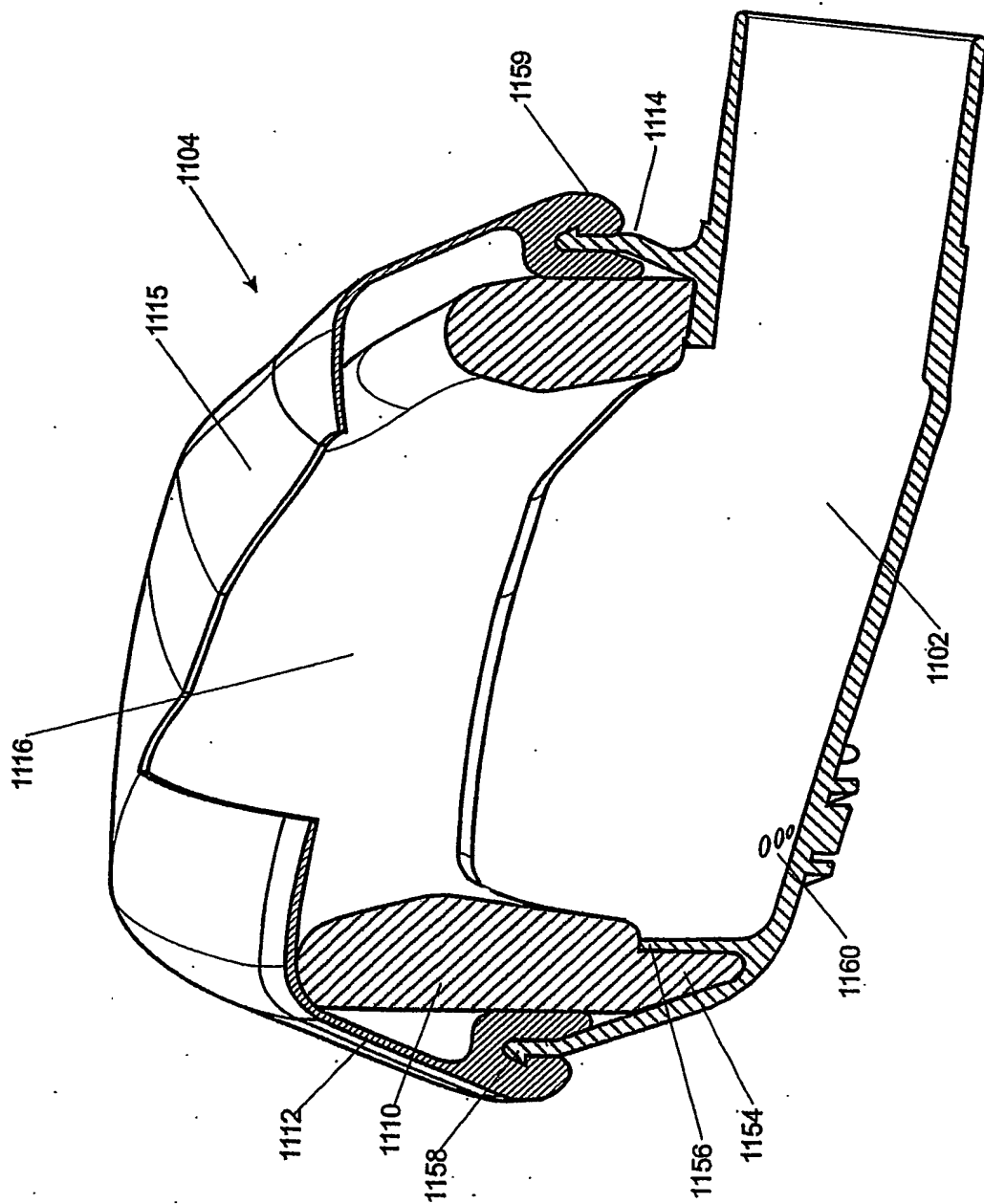


Figure 4

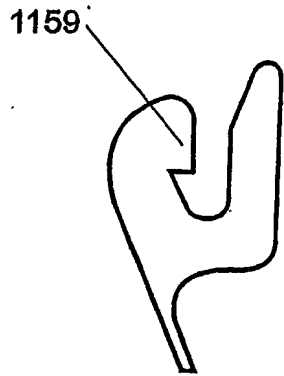


Figure 5

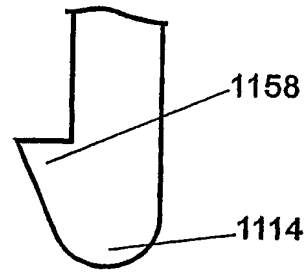


Figure 6

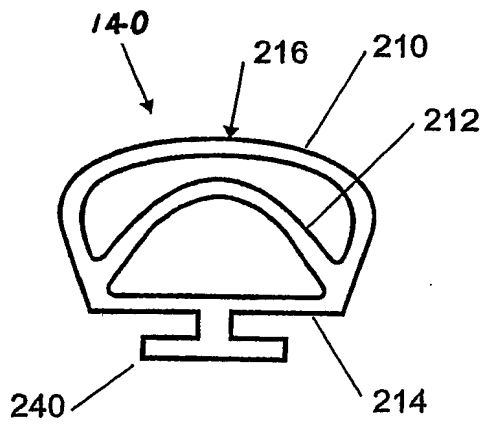


Figure 8

Prior Art

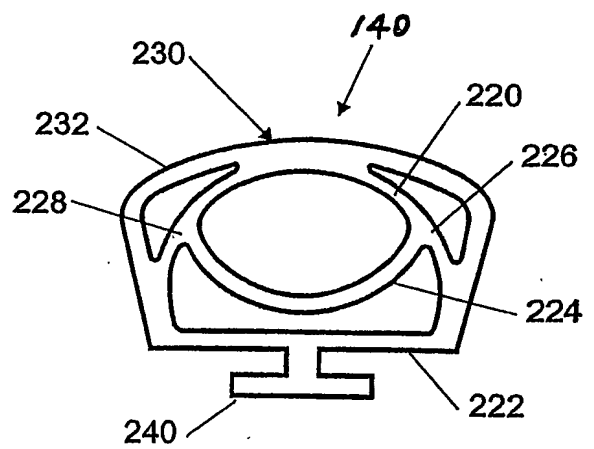


Figure 10

Prior Art

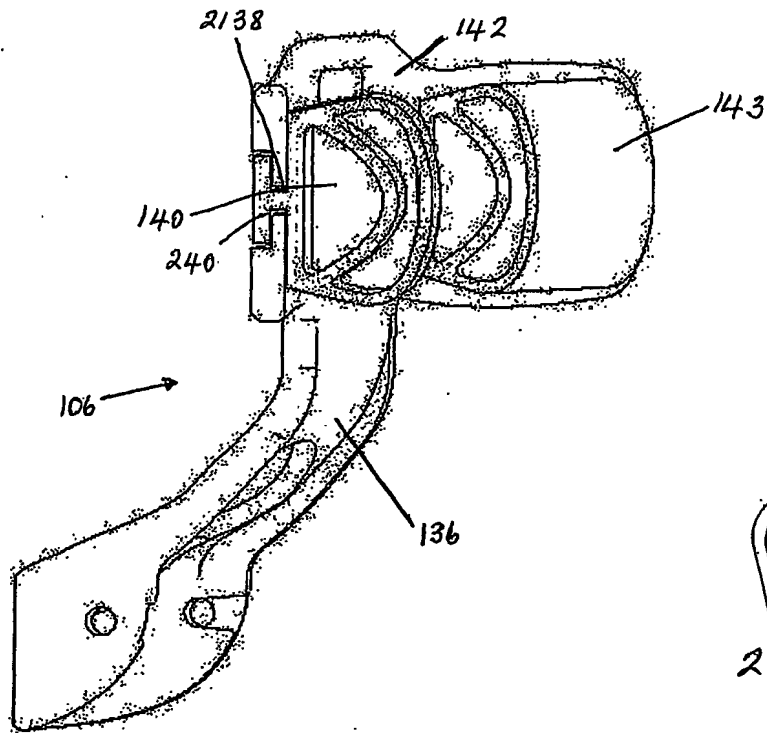


Figure 7
Prior Art

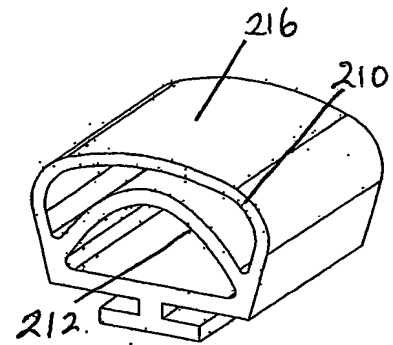


Figure 9
Prior Art

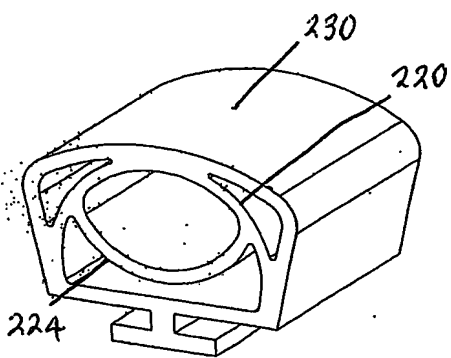


Figure 11
Prior Art

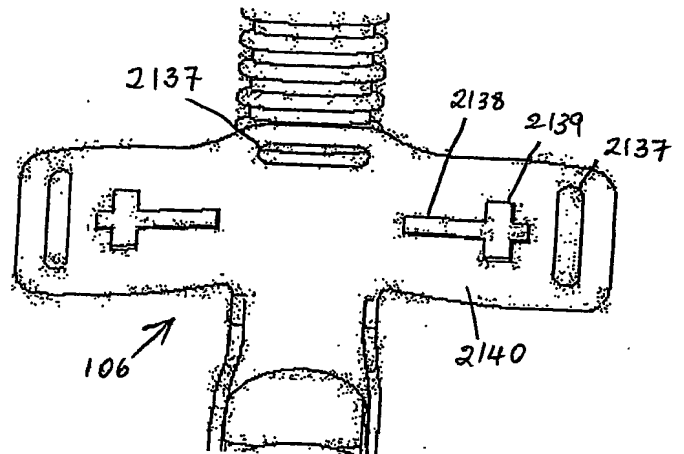


Figure 12
Prior Art

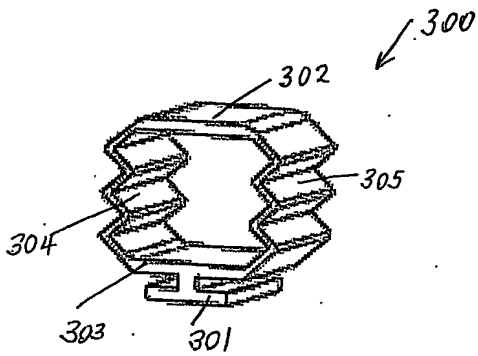


Figure 13

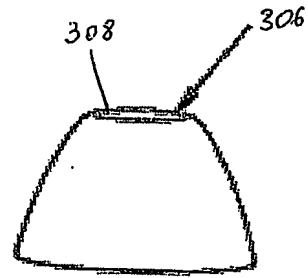


Figure 14

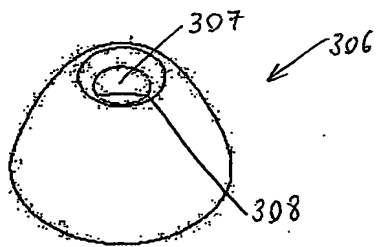


Figure 15

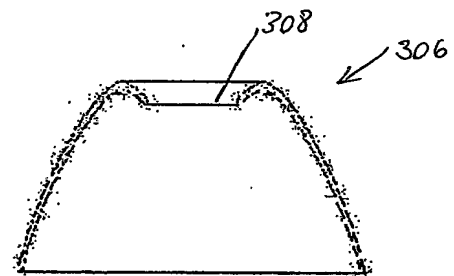


Figure 16

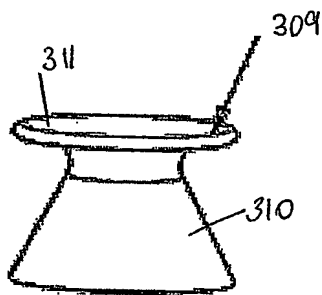


Figure 17

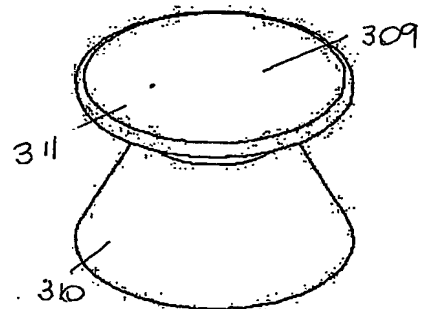


Figure 18

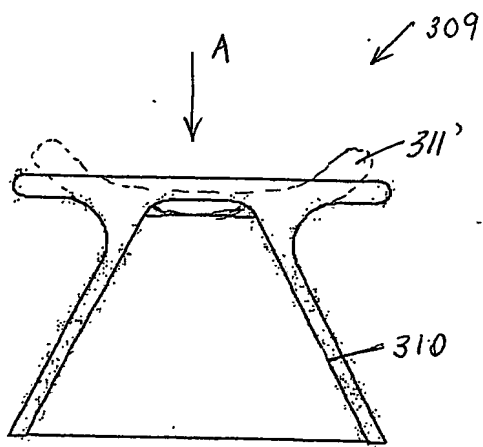


Figure 19

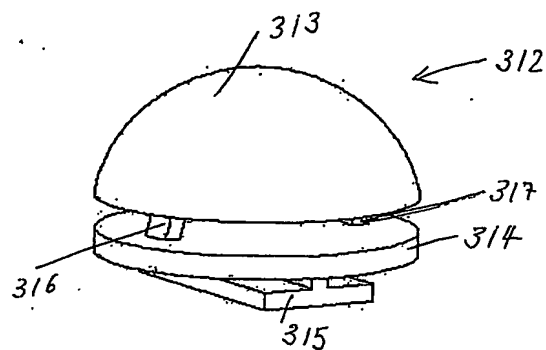


Figure 20

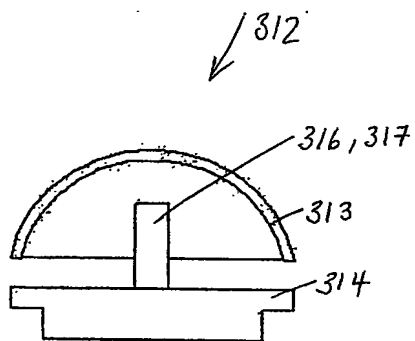


Figure 21

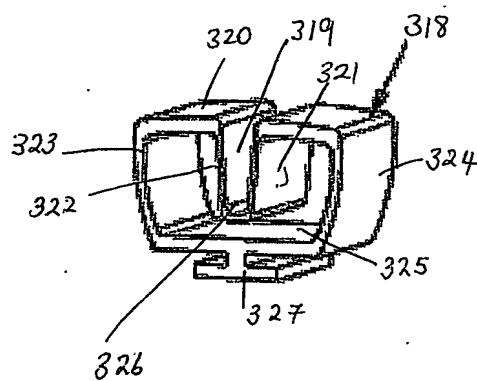


Figure 22

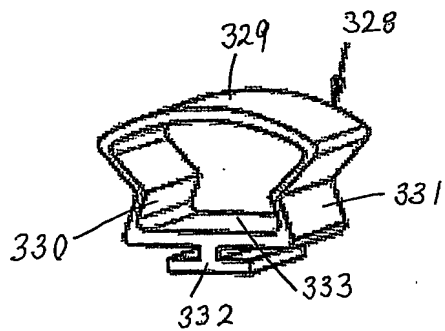


Figure 23

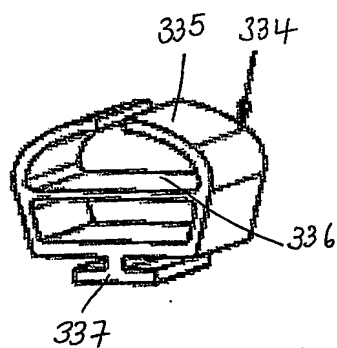


Figure 24

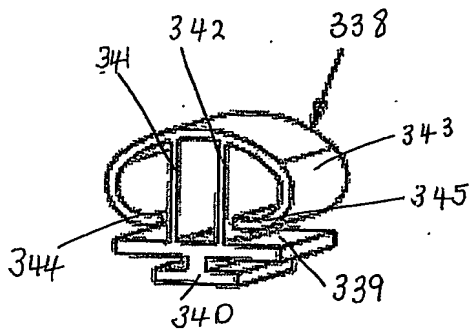


Figure 25

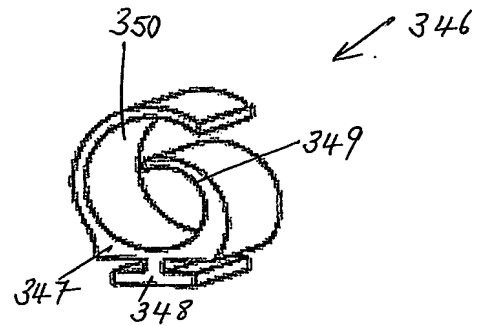


Figure 26

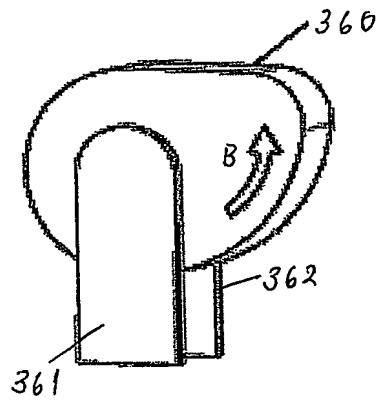


Figure 27

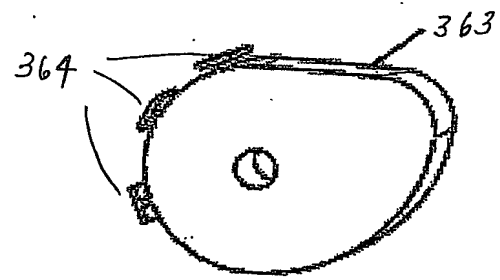


Figure 28

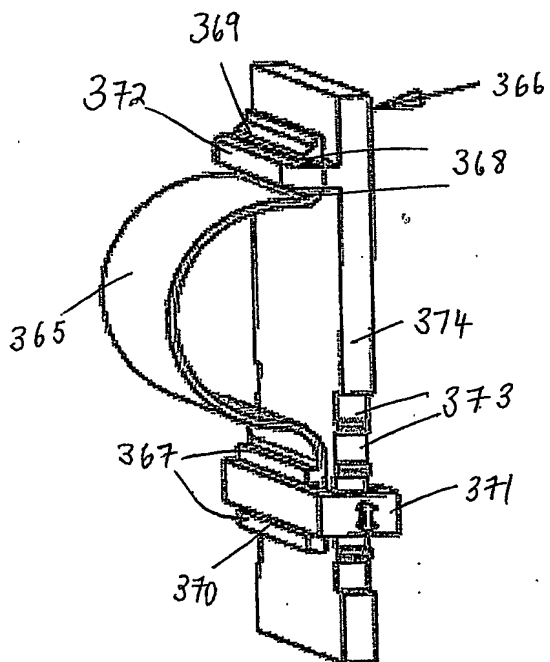


Figure 29

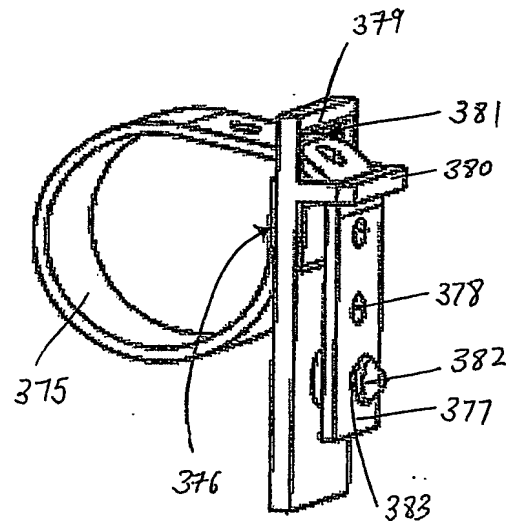
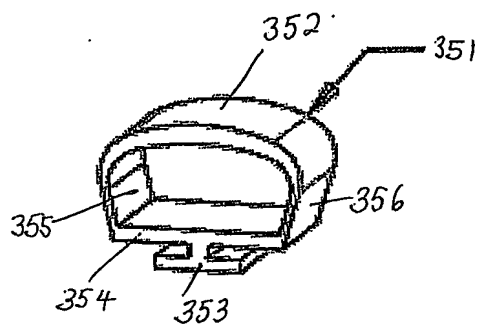
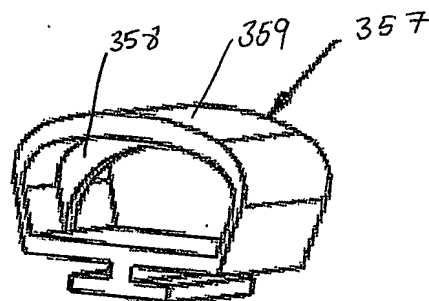
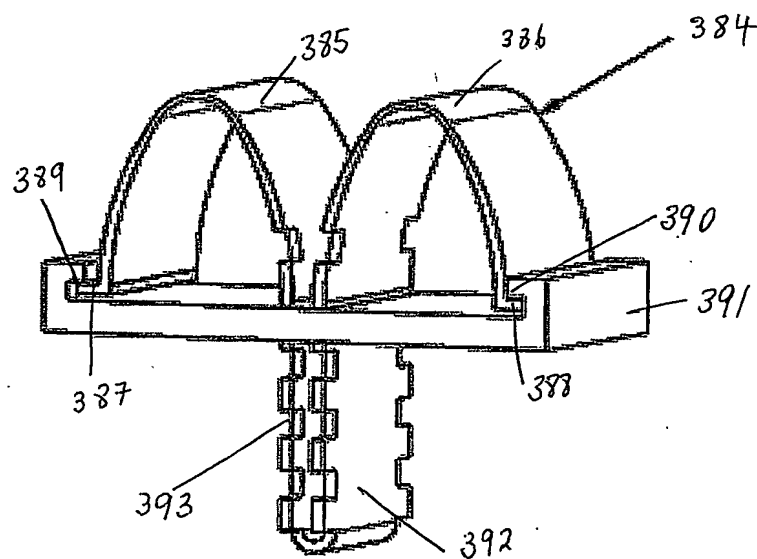


Figure 30

**Figure 31****Figure 32****Figure 33**